

Applicant : Hynda Kleinman et al.  
Serial No. : 09/772,445  
Filed : January 29, 2001  
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Attorney's Docket No.: 08830-056001 / E-131-98/0  
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### AMENDMENT

Please amend the above-captioned application as follows:

#### ***In The Specification:***

*Please amend the specification as follows:*

Delete the title and insert therefor:

--COMPOSITIONS AND METHODS FOR PROMOTING WOUND HEALING  
AND TISSUE REPAIR--

On page 1, after the "Statement as to Federally Sponsored Research" section, after the heading "Cross Reference to Related Applications," please replace the paragraph spanning lines 7 to 9, in its entirety with:

B1  
This application claims the benefit of priority of an international application filed as PCT serial number PCT/US99/17282, filed July 29, 1999, designating the United States, which claims the benefit of priority under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 60/094,690. The aforementioned applications are explicitly incorporated herein by reference in their entirety and for all purposes.

#### ***In The Claims:***

Please cancel claims 41 to 44, 45 to 46 and 51 to 52, without prejudice.

Please add the following new claims:

B2  
68. (NEW) A method for reducing inflammation in a subject in need of such treatment comprising administering to the subject an inflammation-reducing effective amount of a composition comprising an amino acid sequence LKKTET, and conservative variants thereof, having anti-inflammatory activity.

69. (NEW) The method of claim 68, wherein the inflammation is present in a tissue selected from the group consisting of a skin tissue, a dermal tissue, an epidermal tissue, an eye tissue, a cornea, a retina, a uro-genital tissue, a gastro-intestinal tissue, a cardiovascular tissue, a muscle tissue, a connective tissue, a neural tissue, a bone tissue, a cartilage tissue, a

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breast tissue, a central nervous system tissue, a pancreatic tissue, a liver tissue and an endometrial tissue.

70. (NEW) The method of claim 68, wherein the inflammation is present in a skin tissue.

71. (NEW) The method of claim 68, wherein the inflammation is present in a dermal tissue.

72. (NEW) The method of claim 68, wherein the inflammation is present in an epidermal tissue.

73. (NEW) The method of claim 68, wherein the inflammation is present in an eye tissue.

74. (NEW) The method of claim 68, wherein the inflammation is present in a corneal tissue.

B2  
Cont  
75. (NEW) The method of claim 68, wherein the inflammation is present in a retina.

76. (NEW) The method of claim 68, wherein the inflammation is present in a uro-genital tissue.

77. (NEW) The method of claim 68, wherein the inflammation is present in a gastro-intestinal tissue.

78. (NEW) The method of claim 68, wherein the inflammation is present in a cardiovascular tissue.

79. (NEW) The method of claim 68, wherein the inflammation is present in a muscle tissue.

80. (NEW) The method of claim 68, wherein the inflammation is present in a connective tissue.

81. (NEW) The method of claim 68, wherein the inflammation is present in a neural tissue.

82. (NEW) The method of claim 68, wherein the inflammation is present in a bone tissue.

83. (NEW) The method of claim 68, wherein the inflammation is present in a cartilage tissue.

84. (NEW) The method of claim 68, wherein the inflammation is present in a breast tissue.

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cont  
85. (NEW) The method of claim 68, wherein the inflammation is present in a central nervous system tissue.

86. (NEW) The method of claim 68, wherein the inflammation is present in a pancreatic tissue.

87. (NEW) The method of claim 68, wherein the inflammation is present in a liver tissue.

88. (NEW) The method of claim 68, wherein the inflammation is present in an endometrial tissue.

89. (NEW) The method of claim 68, wherein the inflammation is present in a disease or condition selected from the group consisting of a wound, a skin lesion or skin wound, an arthritis, an osteoporosis, a musculo-skeletal disorder, a burn, an ulcer or an ulceration, a pressure ulcer, a diabetic ulcer, a neurological disease, a neurodegenerative disease, a nerve disease, a bone disease, a heart disease, an eye disease, corneal damage, retinal damage, skin damage, a cardiovascular disease, an ischemia, an atherosclerosis, a fibrotic disorder, a sclerotic disorder, a cancer and a cell proliferative disorder.

90. (NEW) The method of claim 68, wherein the inflammation is present in a wound.

91. (NEW) The method of claim 90, wherein the wound comprises a skin wound.

92. (NEW) The method of claim 68, wherein the inflammation is present in a skin lesion.

93. (NEW) The method of claim 68, wherein the inflammation is present in an arthritis.

94. (NEW) The method of claim 68, wherein the inflammation is present in an osteoporosis.

95. (NEW) The method of claim 68, wherein the inflammation is present in a musculo-skeletal disorder.

96. (NEW) The method of claim 68, wherein the inflammation is present in a burn.

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cont

97. (NEW) The method of claim 68, wherein the inflammation is present in an ulcer or an ulceration.

98. (NEW) The method of claim 97, wherein the ulceration comprises a pressure ulcer or a diabetic ulcer.

99. (NEW) The method of claim 68, wherein the inflammation is present in a neurological disease.

100. (NEW) The method of claim 68, wherein the inflammation is present in a neurodegenerative disease

101. (NEW) The method of claim 68, wherein the inflammation is present in a nerve disease.

102. (NEW) The method of claim 68, wherein the inflammation is present in a bone disease.

103. (NEW) The method of claim 68, wherein the inflammation is present in a heart disease.

104. (NEW) The method of claim 68, wherein the inflammation is present in an eye disease.

105. (NEW) The method of claim 68, wherein the inflammation is present in a damaged corneal.

106. (NEW) The method of claim 68, wherein the inflammation is present in a damaged retina.

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cont

107. (NEW) The method of claim 68, wherein the inflammation is present in a damaged skin.

108. (NEW) The method of claim 68, wherein the inflammation is present in a cardiovascular disease.

109. (NEW) The method of claim 68, wherein the inflammation is present in an ischemia.

110. (NEW) The method of claim 68, wherein the inflammation is present in an atherosclerosis.

111. (NEW) The method of claim 68, wherein the inflammation is present in a fibrotic disorder.

112. (NEW) The method of claim 68, wherein the inflammation is present in a sclerotic disorder.

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Cont  
113. (NEW) The method of claim 68, wherein the inflammation is present in a cancer.

114. (NEW) The method of claim 68, wherein the inflammation is present in a cell proliferative disorder.

115. (NEW) The method of claim 68, wherein the composition comprising the amino acid sequence LKKTET consists essentially of thymosin  $\beta$ 4 or an isoform of thymosin  $\beta$ 4.

116. (NEW) The method of claim 68, wherein the composition is administered by a route selected from the group consisting of an injection, a surgery, a catheter, a topical administration, a local injection, an inhalation, a systemic administration, an oral administration

an intranasal administration, an aerosol administration, an intravenous administration, an intraperitoneal administration, an intramuscular administration, an intracavity administration and a transdermal administration.

117. (NEW) The method of claim 68, wherein the composition is administered by an injection.

118. (NEW) The method of claim 68, wherein the composition is administered by a surgery.

119. (NEW) The method of claim 68, wherein the composition is administered by a catheter.

120. (NEW) The method of claim 68, wherein the composition is administered by a topical administration.

121. (NEW) The method of claim 68, wherein the composition is administered by a local injection,

122. (NEW) The method of claim 68, wherein the composition is administered by inhalation,

123. (NEW) The method of claim 68, wherein the composition is administered by systemic administration.

124. (NEW) The method of claim 68, wherein the composition is administered by oral administration,

125. (NEW) The method of claim 68, wherein the composition is administered by intranasal administration.

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cont

126. (NEW) The method of claim 68, wherein the composition is administered by aerosol administration

127. (NEW) The method of claim 68, wherein the composition is administered by intravenous administration.

128. (NEW) The method of claim 68, wherein the composition is administered by intraperitoneal administration.

129. (NEW) The method of claim 68, wherein the composition is administered by intramuscular administration.

130. (NEW) The method of claim 68, wherein the composition is administered by an intracavity administration.

131. (NEW) The method of claim 68, wherein the composition is administered by transdermal administration.

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Cont

132. (NEW) The method of claim 68, wherein the composition comprises a formulation comprising an excipient or a composition selected from the group consisting of saline, sterile water, a sodium chloride solution, lactated Ringer's intravenous, Ringer's dextrose, dextrose and sodium chloride, lactated Ringer's intravenous polyalkylene glycol, polyethylene glycol, vegetable oil, hydrogenated naphthalene, lactide polymer, lactide/glycolide copolymer, polyoxethylene-polyoxypropylene, polyoxyethylene-9-lauryl ether, glycocholate and deoxycholate, phosphatidyl, phosphatidylglycerol, phosphatidylcholine, phosphatidylserine, phosphatidylethanolamine, sphingolipids, cerebroside, gangliosides; phosphatidylcholine, dipalmitoylphosphatidylcholine, distearoylphosphatidylcholine, injectable organic ester, ethyl oleate, an alcoholic/aqueous solution, an alcoholic/aqueous emulsion, an alcoholic/aqueous suspension.

133. (NEW) The method of claim 1, wherein the wound is in a tissue selected from the group consisting of a skin tissue, a dermal tissue, an epidermal tissue, an eye tissue, a cornea, a retina, a uro-genital tissue, a gastro-intestinal tissue, a cardiovascular tissue, a muscle tissue, a connective tissue, a neural tissue, a bone tissue, a cartilage tissue, a breast tissue, a central nervous system tissue, a pancreatic tissue, a liver tissue, a reticulo-endothelial system (RES) tissue and an endometrial tissue.

134. (NEW) The method of claim 1, wherein the wound is present in a disease or condition selected from the group consisting of an arthritis, an osteoporosis, a musculo-skeletal disorder, a burn, an ulcer or an ulceration, a pressure ulcer, a diabetic ulcer, a skin lesion or disease, a neurological disease, a neurodegenerative disease, a nerve disease, a bone disease, a heart disease, an eye disease, corneal damage, retinal damage, skin damage, a cardiovascular disease, an ischemia, an atherosclerosis, a fibrotic disorder, a sclerotic disorder, a cancer and a cell proliferative disorder.

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cont  
135. (NEW) The method of claim 1, wherein the composition is administered by a route selected from the group consisting of an injection, a surgery, a catheter, a topical administration, a local injection, an inhalation, a systemic administration, an oral administration, an intranasal administration, an aerosol administration, an intravenous administration, an intraperitoneal administration, an intramuscular administration, an intracavity administration and a transdermal administration.

136. (NEW) The method of claim 1, wherein the composition comprises a formulation comprising an excipient or a composition selected from the group consisting of saline, sterile water, a sodium chloride solution, lactated Ringer's intravenous, Ringer's dextrose, dextrose and sodium chloride, lactated Ringer's intravenous polyalkylene glycol, polyethylene glycol, vegetable oil, hydrogenated naphthalene, lactide polymer, lactide/glycolide copolymer, polyoxethylene-polyoxypropylene, polyoxyethylene-9-lauryl ether, glycocholate and deoxycholate, phosphatidyl, phosphatidylglycerol, phosphatidylcholine, phosphatidylserine,